Docket No.: **32783A- US-NP**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Carney et al.

APPLICATION NO: 10/722,256

FILED: November 25, 2003

FOR: Medical Devices Having Antimicrobial Coatings Thereon

Art Unit: 1612

Examiner: Farzaneh, Shahrzad

MS: Appeal Brief- Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

AMENDED BRIEF ON APPEAL

TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Sir:

Pursuant to 37 C.F.R. 41.37 Appellants respectfully submit this Amended Brief in support of their Appeal of Examiner Shahrzad Farzaneh's Rejection of claims 1-5 and 16-17 which was issued on an advisory action mailed on June 2, 2008. This Amended Brief is submitted in response to the Notice of Non-Compliant Brief mailed by the Office on September 19, 2008 which stated that Appellants' Brief filed September 5, 2008 was deficient for failing to contain a concise statement of each ground of rejection presented for review— ie, claims 6, 18 are cancelled.

The Notice of Non-Compliant Brief set out a 1-month time for reply. Appellants submit that this Amended Brief, filed October 17, 2008, is timely filed. However, should it be determined that any fees are due, please charge such fees to deposit account number 50-2965 in the name of Ciba Vision.

Real Party in Interest

The present Application has been assigned to the Novartis AG.

Related Appeals and Interferences

There are no other appeals or interferences known to Appellants, their legal representatives or assignees which will directly affected by or have a bearing on the Board's decision on this appeal.

Status of the Claims

Claims 1-5 and 16-17 remain in the application with claims 1-5 and 16-17 being finally rejected. Claims 1-5 and 16-17 are on appeal and claims 6-15 and 18-20 have been cancelled.

Status of Amendments Filed Subsequent to Final rejection

In their After-Final paper filed April 17, 2008, Appellants requested cancellation of claims 8-9 and amendment of claims 1 and 16. The Examiner indicated, in the Advisory Action dated June 2, 2008, that the proposed amendments will be entered for the purposes of appeal.

Summary of Claimed Subject Matter

As claimed in independent claim 1, the present invention provides a contact lens comprising a core material which is a silicone-containing hydrogel material (please see, e.g., as described in the application specification on page 8, lines 14-18 and/or page 9, lines 8-12) and an antimicrobial LbL coating that is not covalently attached to the core material (please see, e.g., as described in the application specification on page 10, lines 12-24), wherein the antimicrobial LbL coating includes:

(a) a polyelectrolyte LbL coating and an peptide layer of one or more antimicrobial peptides (please see, e.g., as described in the application specification on page 19, lines 1-7), wherein the polyelectrolyte LbL coating is composed of

(i) at least one layer of a first polyionic material, or

(ii) at least one layer of the first polyionic material and at least one layer of a second polyionic material having charges opposite of the charges of the first polyionic material,

wherein said first and second polyionic materials, independently of each other, have functional groups which provide reactive sites, and wherein the peptide layer of one or

more antimicrobial peptides are covalently attached to the LbL coating through the reactive sites, (please see, e.g., as described in the application specification on page 19, lines 1-22)

wherein the antimicrobial LbL coating imparts to the core material an increased surface hydrophilicity. (please see, e.g., as described in the application specification on page 10, lines 7-11)

As claimed in independent claim 16, the present invention also provides a contact lens comprising a layer of one or more antimicrobial peptides covaletly attached to the contact lens (please see, e.g., as described in the application specification on page 19, lines 1-7), wherein each of said one or more antimicrobial peptides has an amino acid sequence selected from the group consisting of Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Gly-Ala-Val-Leu-Lys-Val-Leu-COOH, Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Gly-Ala-Val-Leu-Lys-Val-Leu–NH_2, Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Glu-Lys-Val-Gly-Gln-Asn- Ile-Arg-Asp-Gly-Ile-Ile-Lys-Ala-Gly-Pro-Ala-Val-Ala-Val- Val-Gly-Gln-Ala-Thr-Gln-Ile-Ala-Lys-NH_2, Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Glu-Lys-Val-Gly-Gln-Asn- Ile-Arg-Asp-Gly-Ile-Ile-Lys-Ala-Gly-Pro-Ala-Val-Ala-Val- Val-Gly-Gln-Ala-Thr-Gln-Ile-Ala-Lys–COOH, Ser-Trp-Leu-Ser-Lys-Thr-Ala-Lys-Lys-Leu-Glu-Asn-Ser-Ala- Lys-Lys-Arg-Ile-Ser-Glu-Gly-Ile-Ala-Ile-Ala-Ile-Gln-Gly-Gly-Pro-Arg, Arg-Arg-Trp-Gln-Trp-Arg-Met-Lys-Lys-Leu-Gly, Arg-Leu-Cys-Arg-Ile-Val-Val-Ile-Arg-Val-Cys-Arg, Ala-Cys-Tyr-Cys-Arg-Ile-Pro-Ala-Cys-Ile-Ala-Gly-Glu-Arg- Arg-Tyr-Gly-Thr-Cys-Ile-Tyr-Gln-Gly-Arg-Leu-Trp-Ala-Phe- Cys-Cys, Ile-Leu-Pro-Trp-Lys-Trp-Pro-Trp-Trp-Pro-Trp-Arg-Arg–COOH, Ile-Leu-Pro-Trp-Lys-Trp-Pro-Trp-Trp-Pro-Trp-Arg-Arg–COOH, and Gly-Ile-Gly-Lys-Phe-Leu-His-Ser-Ala-Lys-Lys-Phe-Gly-Lys- Ala-Phe-Val-Gly-Glu-Ile-Met-Asn-Ser (please see, e.g., as described in the application specification on page 10, line 32 through page 11, line 25), substitution analogs thereof in which one or more amino acid residues have been replaced by a conservative amino acid substitutions to provide equal or better antimicrobial activity, and deletion analogs thereof in which one or more amino acid residues have been deleted to provide equal or better antimicrobial acitivity (please see, e.g., as described in the application specification on page 11, line 32 through page 12, line 6).

Grounds of Rejection to be Reviewed on Appeal

Ground 1. Claim 1 stands finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over US Patent Publication 2001/0045676 to Winterton, et al. and in view of US

Patent No. 5213801 to Sakuma et al. in further view of US Patent No. 4933410 to Okrongly. 5,508,317).

Ground 2. Claims 2, 4, 5 and 17-18 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over US Patent Publication 2001/0045676 to Winterton, et al. and in view of US Patent No. 5213801 to Sakuma et al. in further view of US Patent No. 4933410 to Okrongly. 5,508,317) in still further view of Diaz-Achirica, et al.

Arguments

Ground 1. Anticipation rejection of claim 1 over US Patent Publication 2001/0045676 to Winterton, et al. and in view of US Patent No. 5213801 to Sakuma et al. in further view of US Patent No. 4933410 to Okrongly. 5,508,317).

Applicants respectfully submit that a prima facie case of obvious has not been established, because the primary reference, alone or in combination with the secondary references, does not disclose or suggest all of the elements of the invention as currently claimed. The Examiner correctly points out that the teachings of first reference (Winterton et al.) and second reference (Sakuma et al) do not describe that the antimicrobial peptides are covalently attached to the LbL coating through the reactive sites (office action dated April 10, 2008, lines 1-3 at page 5). However, Applicants respectfully disagree with the Examiner in the office action of April 10, 2008 regarding that "the third reference (Okrongly) teaches the principle of functionalizing the surface for attachment of various proteins. The principle will be the same whether the protein is attached to polystyrene or any material." (office action dated April 10, 2008, 2nd full paragraph at page 6). Please note that protein attaching to functionalized polystyrene does not satisfy the requirement of "said first and second polyionic materials, independently of each other, have functional groups which provide reactive sites, and wherein the peptide layer of one or more antimicrobial peptides are covalently attached to the LbL coating through the reactive sites" as recited in the claim 1. The polystyrene is not a polyionic material recited in the claim 1.

The third reference (Okrongly) discloses that "[w]ith the increasing expansion of biological research and commercial biological applications, there has been a concomitant increasing need for laboratory equipment capable of specifically binding to complementary ligands and receptors. In order to provide solid substrates, particularly labware, for specific

complex formation, it is necessary to bind a wide variety of ligands and receptors, frequently proteins, to the surface." (Column 1, lines 13-20). "The solid substrate may exist in any form, including, but not limited to: reaction vessels, reagent tubes, beakers, cuvettes, columns, microtiter plates, Petri dishes, fabricated articles, beads, rods, fibers, strands, membranes, discs, or plates. The articles are normally formed by molding polystyrene at least substantially free of crosslink, usually resulting in a clear, smooth surface," (column 2, lines 48-55). To achieve the goal, the third reference also discloses "formed substantially uncrosslinked polystyrene products are functionalized employing hydroxymethylamides for electrophilic substitution on the phenyl groups. The resulting functionalized polystyrene may be used for reacting with a wide variety of functionalities, particularly associated with macromolecules, to provide for a high density of covalently bonded macromolecules." (column 2, lines 3-13).

The failure of an asserted combination to teach or suggest each and every element of a claim remains fatal to an obviousness rejection under 35 U.S.C. § 103, despite any recent revision to the Manual of Patent Examining Procedure (MPEP)..

Section 2143.03 of the MPEP requires the "consideration" of every claim element in an obviousness determination. To render claim 1 unpatentable, however, the Office must do more than merely "consider" each and every element for this claim. Instead, the asserted combination of the patents or patent application publication to Winterton, et al. and Sakuma et al. and Okrongly must also teach or suggest *each and every claim element. See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish *prima facie* obviousness of a claimed invention, all the claim elements must be taught or suggested by the prior art). Indeed, as the Board of Patent Appeal and Interferences has recently confirmed, a proper obviousness determination requires that an Examiner make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *See In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). Further, the necessary presence of all claim element is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ... ascertaining the differences between *the claimed invention* and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added). Indeed, Applicant submits that this is why Section 904 of the MPEP instructs Examiners to conduct an art search that covers "the invention *as described and claimed.*" (emphasis added). Lastly, Applicant respectfully directs attention to MPEP § 2143, the instructions of which buttress the conclusion that obviousness requires at least a suggestion of all of the elements of a claim,

since the Supreme Court in *KSR Int'l v. Teleflex Inc.* stated that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (*quoting In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

In sum, it remains well-settled law that obviousness requires at least a suggestion of all of the element in a claim. *See In re Wada and Murphy, citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

For these reasons, it is Appellants' position that the obviousness rejection of claim 1 over US Patent Publication 2001/0045676 to Winterton, et al. and in view of US Patent No. 5213801 to Sakuma et al. in further view of US Patent No. 4933410 to Okrongly. 5,508,317) has been shown to be untenable and should be reversed by the Board.

Ground 2. Obviousness rejection of claims 2, 4, 5 and 16-17 over US Patent Publication 2001/0045676 to Winterton, et al. and in view of US Patent No. 5213801 to Sakuma et al. in further view of US Patent No. 4933410 to Okrongly. 5,508,317) and Diaz-Achirica.

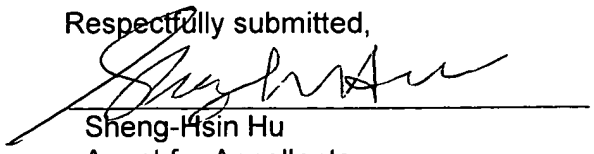
For the same reasons provided at the ground 1 argument, it is Appellants' position that the obviousness rejection of claims 2, 4, 5 and 16-17 over US Patent Publication 2001/0045676 to Winterton, et al. and in view of US Patent No. 5213801 to Sakuma et al. in further view of US Patent No. 4933410 to Okrongly. 5,508,317 and in still further view of Diaz-Achirica.

For these reasons, it is Appellants' position that the obviousness rejection of claim 1 over US Patent Publication 2001/0045676 to Winterton, et al. and in view of US Patent No. 5213801 to Sakuma et al. in further view of US Patent No. 4933410 to Okrongly. 5,508,317), and in still further review of Diaz-Achirica has been shown to be untenable and should be **reversed** by the Board.

Conclusion

For the reasons stated above it is Appellants' position that the all of the rejections of their claims have been shown to be untenable and should be **reversed** by the Board. That is, for the reasons set forth above, it is respectfully submitted that the rejections under 35 U.S.C. §103 should be reversed. It is respectfully submitted that Appellant's claimed invention is not obvious from the cited references.

Respectfully submitted,



Sheng-Hsin Hu
Agent for Appellants
Reg. No. 50,328

Ciba Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097
(678) 415-3171

Date: Oct. 17, 2008

Appendix – The Claims on Appeal

1. (Rejected) A contact lens comprising a core material which is a silicone-containing hydrogel material and an antimicrobial LbL coating that is not covalently attached to the core material, wherein the antimicrobial LbL coating includes:
   (a) a polyelectrolyte LbL coating and an peptide layer of one or more antimicrobial peptides, wherein the polyelectrolyte LbL coating is composed of
      (i) at least one layer of a first polyionic material, or
      (ii) at least one layer of the first polyionic material and at least one layer of a second polyionic material having charges opposite of the charges of the first polyionic material,
   wherein said first and second polyionic materials, independently of each other, have functional groups which provide reactive sites, and wherein the peptide layer of one or more antimicrobial peptides are covalently attached to the LbL coating through the reactive sites, wherein the antimicrobial LbL coating imparts to the core material an increased surface hydrophilicity.
2. (Rejected) A contact lens of claim 1, wherein said one or more antimicrobial peptides are selected from the group consisting of Cecropin A melittin hybrid, indolicidin, lactoferricin, Defensin 1, Bactenecin (bovin), Magainin 2, mutacin 1140, functionally equivalent or suprior analogs thereof, and mixtures thereof.
3. (Rejected) A contact lens of claim 1, wherein said one or more antimicrobial peptides are selected from the group consisting of Cecropin A melittin hybrid and indolicidin.
4. (Rejected) A contact lens of claim 2, wherein the medical device comprises a polyelectrolyte LbL coating and an peptide layer of one or more antimicrobial peptide, wherein the polyelectrolyte LbL coating is composed of (i) at least one layer of a first polyionic material or (ii) at least one layer of the first polyionic material and at least one layer of a second polyionic material having charges opposite of the charges of the first polyionic material, wherein said first and second polyionic materials, independently of each other, have functional groups which provide reactive sites, and wherein the peptide layer of one or more antimicrobial peptides are covalently attached to the LbL coating through the reactive sites.
5. (Rejected) A contact lens of claim 4, wherein one of the first and second polyionic materials is a polyanionic material and the other is a polycationic material, wherein the polyanionic material is selected from the group consisting of polyacrylic acid, polymethacrylic acid, poly(thiophen-3-acetic acid), poly(4-styrenesulfonic acid), PAMAM dendrimers, PAAm-co-

PAA, PVP-co-PAA, hyaluronic acid, glycosaminoglycanes, fucoidan, poly-aspartic acid, poly-glutamic acid, carboxymethyl cellulose, carboxymethyl dextrans, alginates, pectins, gellan, carboxyalkyl chitins, carboxymethyl chitosans, sulfated polysaccharides, derivatives thereof and mixtures thereof, wherein the polycationic material is selected from the group consisting of poly(allylamine hydrochloride), poly(ethyleneimine), poly(vynylbenzyltriamethylamine), polyaniline, polypyrrole, poly(pyridinium acetylene), polyquat, polyaminoamide, poly-ε-lysine, albumin or collagen, aminoalkylated polysaccharides, derivatives thereof and mixtures thereof.

6. (Canceled)
7. (Canceled)
8. (Canceled)
9. (Canceled)
10. (Cancelled)

11-15. (Cancelled)

16. (Rejected) A contact lens comprising a layer of one or more antimicrobial peptides covaletly attached to the contact lens, wherein each of said one or more antimicrobial peptides has an amino acid sequence selected from the group consisting of Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Gly-Ala-Val-Leu-Lys-Val-Leu-COOH, Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Gly-Ala-Val-Leu-Lys-Val-Leu–NH_2, Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Glu-Lys-Val-Gly-Gln-Asn- Ile-Arg-Asp-Gly-Ile-Ile-Lys-Ala-Gly-Pro-Ala-Val-Ala-Val- Val-Gly-Gln-Ala-Thr-Gln-Ile-Ala-Lys-NH_2, Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Glu-Lys-Val-Gly-Gln-Asn- Ile-Arg-Asp-Gly-Ile-Ile-Lys-Ala-Gly-Pro-Ala-Val-Ala-Val- Val-Gly-Gln-Ala-Thr-Gln-Ile-Ala-Lys–COOH, Ser-Trp-Leu-Ser-Lys-Thr-Ala-Lys-Lys-Leu-Glu-Asn-Ser-Ala- Lys-Lys-Arg-Ile-Ser-Glu-Gly-Ile-Ala-Ile-Ala-Ile-Gln-Gly-Gly-Pro-Arg, Arg-Arg-Trp-Gln-Trp-Arg-Met-Lys-Lys-Leu-Gly, Arg-Leu-Cys-Arg-Ile-Val-Val-Ile-Arg-Val-Cys-Arg, Ala-Cys-Tyr-Cys-Arg-Ile-Pro-Ala-Cys-Ile-Ala-Gly-Glu-Arg- Arg-Tyr-Gly-Thr-Cys-Ile-Tyr-Gln-Gly-Arg-Leu-Trp-Ala-Phe- Cys-Cys, Ile-Leu-Pro-Trp-Lys-Trp-Pro-Trp-Trp-Pro-Trp-Arg-Arg–COOH, Ile-Leu-Pro-Trp-Lys-Trp-Pro-Trp-Trp-Pro-Trp-Arg-Arg–COOH, and Gly-Ile-Gly-Lys-Phe-Leu-His-Ser-Ala-Lys-Lys-Phe-Gly-Lys- Ala-Phe-Val-Gly-Glu-Ile-Met-Asn-Ser, substitution analogs thereof in which one or more amino acid residues have been replaced by a conservative amino acid substitutions to provide equal or better antimicrobial activity, and deletion analogs thereof in which one or more amino acid residues have been deleted to provide equal or better antimicrobial acitivity.

17. (Rejected) A contact lens of claim 16, wherein each of said one or more antimicrobial peptides has an amino acid sequence selected from the group consisting of Lys-Trp-Lys-

Leu-Phe-Lys-Lys-Ile-Gly-Ala-Val-Leu-Lys-Val-Leu-COOH, Lys-Trp-Lys-Leu-Phe-Lys-Lys-Ile-Gly-Ala-Val-Leu-Lys-Val-Leu–NH_2, Ile-Leu-Pro-Trp-Lys-Trp-Pro-Trp-Trp-Pro-Trp-Arg-Arg–COOH, and Ile-Leu-Pro-Trp-Lys-Trp-Pro-Trp-Trp-Pro-Trp-Arg-Arg–COOH.

18. (Cancelled)

19-20. (Cancelled).

Appendix – Evidence

None

Appendix – Related Proceedings

None